

EXECUTIVE SUMMARY

PURPOSE

To describe and assess the role of organ procurement organizations in procuring tissue for transplantation, and to identify vulnerabilities associated with that involvement.

BACKGROUND

Human tissue grafts, from perhaps 10,000 donors, benefit as many as a half-million people annually. The great majority of these transplanted tissues are bones, bone products, or other parts of the musculo-skeletal system, such as tendons, fascia, and soft tissues. Consequently, we focus this inspection report on bone and musculo-skeletal tissue, and we use the term "tissue" to refer to these.

In December 1993, the Food and Drug Administration (FDA) regulated tissue banking for the first time by requiring testing for infectious disease, donor screening, and record keeping. New York, Florida, and California now regulate tissue banking at the State level.

Organ procurement organizations (OPOs) are responsible for recovering organs from donors. The National Organ Transplant Act requires that OPOs must also "have arrangements to cooperate with tissue banks for the retrieval, processing, preservation, storage, and distribution of tissues as may be appropriate to assure that all useable tissues are obtained from potential donors." While OPOs see organ procurement as their primary function, to the extent that statutory expectations for tissue recovery are not met, opportunities for donating and using tissues are lost.

This inspection report focuses on the supply of tissues and the role of the OPOs in procuring tissue. The Public Health Service (PHS) estimates that 125 bone banks in the United States recover, process, and/or distribute bone for transplantation.

Federal law requires that OPOs have arrangements with tissue banks for tissue procurement. How well they perform this role can have a significant bearing on recovering a sufficient supply of high quality tissue for transplantation. The OPOs already are involved in tissue banking by virtue of their involvement in organ procurement. As much as 60 percent of bone tissue used for transplantation comes from donors of solid organs.

We conducted a mail survey of all Medicare-certified OPOs, with a response rate of 95 percent; interviewed staff from 15 OPOs by telephone; made site visits to four OPOs, as well as tissue banks and hospitals in their service areas; interviewed Federal officials from PHS and the Health Care Financing Administration (HCFA) and staff from relevant associations; conducted a focus group with directors of five tissue banks; and reviewed pertinent Federal reports, legislation, and literature.

FINDINGS

All 62 OPOs responding to our survey participate in tissue recovery to some degree.

- Thirty-four OPOs refer potential donors to tissue banks.
- Twenty-eight OPOs recover tissue themselves.

The OPOs' commitment to tissue recovery varies widely. Performance data show that they have not taken full advantage of opportunities to obtain tissue from potential donors.

As part of our review, we developed three performance indicators to measure the OPOs' involvement in tissue recovery:

Organ Donors Referred to Tissue Banks: For the 34 OPOs that refer potential tissue donors to tissue banks, we measured the percentage of organ donors who were referred for tissue donation. This performance indicator assesses the degree to which an OPO actually refers its organ donors for tissue donation.

- *Three of these OPOs reported that they referred all of their organ donors for tissue recovery. At the other extreme, 2 OPOs reported that they referred fewer than 20 percent of organ donors for tissue donation.*

Organ Donors Providing Tissues: For the 28 OPOs that recover tissue, we measured the percentage of organ donors from whom they recovered both organs and tissues. This performance indicator assesses the emphasis that an OPO gives to organ donors as a source of tissue.

- *The percentage of organ donors from whom these OPOs recovered both organs and tissue ranged from a high of 43 percent to a low of 6 percent.*

Ratio of Tissue Donors to Organ Donors: For the 28 OPOs that recover tissue, we measured the ratio of tissue donors to organ donors. This performance indicator assesses the attention that an OPO places on nonorgan donors as a source of tissue.

- *Three of these OPOs reported more than 150 tissue donors for every 100 organ donors. At the other extreme, 3 OPOs procured tissue from fewer than 20 tissue donors for every 100 organ donors.*

Tensions exist between organ procurement and tissue recovery. If these tensions intensify, they could have adverse consequences for the supply of tissues and of organs.

- Inherent differences between organ procurement and tissue recovery (in urgency, prestige, and organization) can limit OPOs' and tissue banks' willingness to work together.
- Competition for donors among multiple tissue banks could threaten hospitals' eagerness to work with OPOs and tissue banks.

Some OPOs and tissue banks have developed effective practices to improve organ and tissue donation.

- Some OPOs and tissue banks are working together to facilitate communication and cooperation. These efforts include a central telephone system to receive all donor referrals and written agreements specifying referral arrangements among OPOs and tissue banks.
- Some OPOs have established programs under which hospitals routinely refer all deaths to the OPO to increase the number of donor referrals.

RECOMMENDATIONS

Our recommendations arise from the statutory requirement that OPOs "have arrangements to cooperate with tissue banks for the retrieval of tissues to assure that all useable tissues are obtained from potential donors." Little national attention has focused on this mandate. The relationship between tissue banks and organ procurement organizations can have a significant impact on overall OPO performance.

The PHS should provide some general oversight and guidance for OPOs regarding their arrangements with tissue banks and their tissue recovery activity.

We encourage PHS to collect routine data about OPO involvement with tissue recovery. The agency could also disseminate information about effective OPO tissue banking practices to improve donation. In addition, we urge PHS to keep a watchful eye on tensions between OPOs and tissue banking to determine if these tensions are jeopardizing the supply of tissues and organs.

The HCFA should include an assessment of OPOs' performance in tissue recovery as part of the OPO recertification process.

The HCFA could utilize performance indicators to assess how well OPOs are meeting the requirement that they have arrangements to cooperate with tissue banks. We recognize that recertification focuses on an OPO's performance with respect to organ procurement and distribution. We believe that some measure of accountability for OPO performance in tissue recovery is also warranted.

COMMENTS

Within the Department of Health and Human Services, we received comments on the draft report from PHS, HCFA, and the Assistant Secretary for Planning and Evaluation (ASPE). We also received comments from the United Network for Organ Sharing (UNOS), the American Association of Tissue Banks (AATB), and the Association of Organ Procurement Organizations (AOPO). Overall, the comments share three major points:

Additional resources would be needed for PHS to provide general oversight and guidance.

The PHS concurs with our recommendation that the agency provide some general oversight and guidance for OPOs regarding their arrangements with tissue banks and their tissue recovery activity. That agency, AATB, and UNOS indicate, however, that additional resources would be needed to implement this recommendation, and ASPE calls it infeasible at this time. We are aware that funding for new initiatives is limited, but we believe that PHS could begin providing general oversight and guidance without incurring extensive new expenditures and without imposing a major reporting burden on agencies or tissue banks. Existing reporting systems can be revised incrementally to obtain these data with a minimum of expense and effort. We would be pleased to work with PHS toward this end.

The specific performance indicators we developed may not be adequate to evaluate OPOs' performance in tissue recovery.

The AATB finds our performance indicators to be reliable indicators of the strength of OPO commitment to tissue recovery from cadaveric donors, but HCFA, ASPE, and AOPO question their adequacy. We developed these indicators from readily available data, but we are confident that other indicators also would show wide variation in OPO performance. We are not wedded to these or other particular performance indicators. Rather, we offer them as a starting point in deliberations to develop performance indicators for OPOs and tissue banking. We encourage HCFA and PHS to collaborate either to modify these indicators or to develop other indicators that will begin to hold OPOs accountable for their activities with regard to tissue recovery.

Including an assessment of OPO performance in tissue recovery as part of the Medicare recertification process is not feasible at present.

Both HCFA and ASPE identify regulatory barriers to including an assessment of OPO performance in tissue recovery as part of OPO Medicare recertification processes. The HCFA notes that such an effort is a long-term initiative, which must be preceded by data collection and development of appropriate and valid performance indicators. We believe that the long lead time that HCFA requires makes a compelling case for initiating this activity soon. Collecting necessary data and developing more refined performance indicators are a precondition for this assessment. Consequently, we urge HCFA to establish an appropriate schedule to carry out such a proposal.